DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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December 18, 2014

Smith & Nephew, Inc.
Ms. Samantha Staubach
Regulatory Affair Specialist I
1450 Brooks Road
Memphis, Tennessee 38116

Re: K143050
Trade/Device Name: VLP Mini-Mod Small Bone Plating System 1.5mm Plates and Screws
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: October 22, 2014
Received: October 23, 2014

Dear Ms. Staubach:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Premarket Notification
Indications for Use Statement

510(k) Number (if known): K143050

Device Name: VLP Mini-Mod Small Bone Plating System 1.5mm Plates and Screws

Indications for Use:

The Smith & Nephew Variable-Angle Locking Mini-Fragment Plating System is indicated for adolescent (12-18 years) and transitional adolescent (18-21 years) subpopulations and adults, as well as patients with osteopenic bone. The Smith & Nephew Variable-Angle Locking Mini-Fragment Plating System is indicated for fracture fixation, arthrodesis, reconstruction, replantation or reduction of small bones and fragments. This system is also indicated for non-load bearing stabilization and reduction of bone fragments in long bones.

Bone plates and bone screws from the Smith & Nephew Variable-Angle Locking Mini-Fragment Plating System are for single use only.

Prescription Use __X__ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

We are smith&nephew

Submitted by:	Smith & Nephew, Inc. Orthopaedic Division 1450 East Brooks Road Memphis, Tennessee 38116
Date of Summary:	October 22, 2014
Contact Person and Address:	Samantha Staubach Regulatory Affairs Specialist I T (901) 399-6132 F (901) 566-7596
Name of Device:	Smith & Nephew, Inc. VLP Mini-Mod Small Bone Plating System 1.5mm Plates and Screws
Common Name:	Bone Plates and Screws
Device Classification Name and Reference:	21 CFR 888.3030 Single/multiple component metallic bone fixation appliances and accessories Class II 21 CFR 888.3040 Smooth or threaded metallic bone fixation fastener Class II
Panel Code:	Orthopedics/87
Product Code:	HRS/HWC

Device Description

The subject premarket notification describes 1.5mm line additions to the VLP Mini-Mod Small Bone Plating System. The subject internal fixation plating system is comprised of assorted implantable, locking bone plates and compatible locking and non-locking bone screws to be used on various small bones and fragments. The VLP Mini-Mod Small Bone Plating System is a subset of the Smith & Nephew Variable-Angle Locking Mini-Fragment Plating System, which was previously cleared via Traditional 510(k) **K132886**. Subject plates consist of groups of devices with a radiused cross-section where the number of holes in the plates will range from 6 through 24. Specific plate designs include Y-plates, T-plates, Straight plates, and Column plates. All described implant devices are manufactured from implant-grade titanium alloy material (Ti-6Al-4V) and designed for single-use. They will be provided in a sterile packaged option and will be sterilized via Gamma irradiation. Bone screws will be offered in both locking and non-locking options in a variety of lengths.

Intended Use

Bone plates and bone screws from the VLP Mini-Mod Small Bone Plating System are intended for use in internal fixation of small bones and small bone fragments and non-load bearing stabilization and reduction of bone fragments in long bones.

Indications for Use

The Smith & Nephew Variable-Angle Locking Mini-Fragment Plating System is indicated for adolescent (12-18 years) and transitional adolescent (18-21 years) subpopulations and adults, as well as patients with osteopenic bone. The Smith & Nephew Variable-Angle Locking Mini-Fragment Plating System is indicated for fracture fixation, arthrodesis, reconstruction, replantation or reduction of small bones and fragments. This system is also indicated for non-load bearing stabilization and reduction of bone fragments in long bones.

Bone plates and bone screws from the Smith & Nephew Variable-Angle Locking Mini-Fragment Plating System are for single use only.

The indications for use for the subject VLP Mini-Mod Small Bone Plating System 1.5mm Plates and Screws are identical to those previously cleared for the Smith & Nephew Variable-Angle Locking Mini-Fragment Plating System.

Technological Characteristics

Device comparisons described in this premarket notification demonstrated that the proposed bone plates and bone screws are substantially equivalent to the legally marketed predicate devices listed below with regard to intended use, indications for use, materials and performance characteristics. The subject VLP Mini-Mod 1.5mm Bone Plates and Screws feature characteristics very similar to the VLP Mini-Mod Small Bone Plating System cleared via K132886, with the primary difference being the 1.5mm size offering. To accommodate for the size difference between the 1.5mm subject plates and the 2.0mm and 2.4mm offerings cleared via K132886, mechanical testing was conducted against the secondary predicates.

Substantial Equivalence Information

When compared to the predicate devices listed below, substantial equivalence is based upon similar function, intended use, indications for use and overall design to the devices listed in the table below.

Table 1: Substantially Equivalent Predicates to the VLP Mini-Mod Small Bone Plating System 1.5mm Plates and Screws

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc.	Smith & Nephew Variable-Angle Locking Mini-Fragment Plating System ***(Primary Predicate)***	K132886	2/4/14
Synthes (USA)	Synthes (USA) 1.5mm Mini Fragment LCP System	K090047	4/1/09
Smith & Nephew, Inc.	Smith & Nephew Bone Plate System	K993106	12/9/99

Summary of Pre-Clinical Testing

- *Finite element analysis (FEA)* was conducted on the proposed 1.5mm bone plate designs to determine the worst case plate as well as the high stress region of the plate to be used for subsequent mechanical testing. The acceptance criteria was met in that the subject bone plates exhibited similar or superior structural strength compared to the existing 1.5mm predicates. Results of the FEA demonstrated that the plates identified for mechanical testing were the appropriate bone plates because they possessed the highest stress concentrations.
- *Four-point bend fatigue testing* was conducted on worst-case examples of the proposed bone plates, as identified through FEA testing. Results of the testing concluded that the number of log cycles to failure achieved by the proposed bone plates met the acceptance criteria in that they were found to be non-inferior to the fatigue log cycles to failure of a previously cleared predicate.
- *Torque-to-failure testing* for the proposed 1.5mm bone screws was conducted per the guidelines of ASTM F543-07. The acceptance criterion was met in that all tested 1.5mm screws met the minimum torsional strength requirement dictated by ASTM F543-07.
- *Axial pull-out testing* was conducted on the subject 1.5mm cortex screws following the guidelines set forth in ASTM F543 with maximum force denoted as pull-out strength. The subject implants met the acceptance criteria in that the maximum pull-out force of the subject screws was non-inferior to the maximum pull-out force of the predicate.

Conclusion

This 510(k) premarket notification is being submitted to request clearance for the VLP Mini-Mod Small Bone Plating System 1.5mm Plates and Screws. Based on the similarities to the predicate components and a review of the mechanical testing performed, the devices are substantially equivalent to the predicate plating systems listed in *Table 1* on page 5-2.